UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,109	03/17/2004	David Cook	Cerus-4900.20	5306

25226 7590 11/24/2006

MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

EXAMINER	
SAUCIER, SANDRA E	
ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 11/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/803,109	COOK ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *10 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 11-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/5/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20 are pending and claims 1-9, 11-19 are considered on the merits. The election of species listed in the response of 10/5/06 are aziridinium ion, glutathione, acridine derivatives. Claims 10 and 20 are withdrawn as not reading on the elected species.

Specification

The disclosure is objected to because of the following informalities: Please update the continuity information, 09/912031 has matured into a patent.

Information Disclosure Statement

The listing of the references on PTO 1449 is incomplete. A proper citation includes AUTHOR, TITLE, JOURNAL, VOLUME, NUMBER, INCLUSIVE PAGES, (month), YEAR. Reference 81 is missing the date of publishing.

References 37, 45, 46, 80, 94 are not found associated with the parent applications. Please submit them for consideration.

MPEP37 CFR 1.98(b) requires that each U.S. patent listed in an information disclosure statement be identified by patentee, patent number, and issue date. Each foreign patent or published foreign patent application must be identified by the country or patent office which issued the patent or published the application, an appropriate document number, and the publication date indicated on the patent or published application. Each publication must be identified by author (if any), title, relevant pages of the publication, date and place of publication. The date of publication supplied must include at least the month and year of publication, except that the year of publication (without the month) will be accepted if the applicant points out in the information disclosure statement that the year of publication is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the particular month of publication is not in issue. The place of publication refers to the name of the journal, magazine, or other publication in which the information being submitted was published.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9, 11-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-56 of U.S. Patent No. 6,270,952 [26]. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are overlapping in scope. Claim 1 of the instant application is encompassed by the issued claim 1.

Claims 1-9, 11-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,709,810 [27]. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are overlapping in scope. Claim 1 of the instant application is broader in scope than the issued claim 1.

Claim Rejections - 35 USC § 112

NEW MATTER

Claims 1-9, 11-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Insertion of the limitation "wherein the compound inactivates at least about 1 log of the pathogen" has no support in the originally filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Thus, the insertion of the expression above is considered to be the insertion of new matter and a broadening of the original disclosure for the above reasons. The original disclosure states that the range is "at least about 3 to 6 logs". Applicants appear to have broadened the range and therefore, broaden the claim with reference to the original disclosure.

INDEFINITE

Claims 1-9, 11-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is inconsistent in that no pathogen is required to be present in the material, but the compound is required to inactivate at least about 1 log of the pathogen. It is suggested that the claim should read--wherein the compound is capable of.... Likewise with claim 9.

Claims 4 and 5 stipulate that the method being performed is *in vitro* and *ex vivo.* This is clearly a method performed in a blood bag or some other type of container for red cells. However, claim 6, recites "*in situ*". It is unclear what this means in the context of the other claims. If applicants are now claiming a method which is performed, for example in an animal, which is a natural position or place for red cells, which is the medical definition of "*in situ*", this raises questions of enablement at least. Please clarify this phrase or delete it.

Claim 7 should read that the compound "further comprises a nucleic acid binding ligand". Since this is an additional group attached the pathogen inactivating moiety.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 11-16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Roth et al. [91].

The claims are directed to a method for treating RBC comprising: adding a pathogen inactivating compound to the RBC, which compound has an electrophilic group which can form a covalent bond with nucleic acid,

adding a quencher to the RBC, which quencher has a nucleophilic group which can form a covalent bond with the electrophilic group of the pathogen inactivating compound, either prior to, simultaneously or within about 20 minutes after the addition of the pathogen inactivating compound.

Roth et al. disclose a method comprising:
adding HN2 (0.65 or 1 mg/ml) to red cells in a blood bag for thirty minutes, adding 0.11M sodium thiosulfate.

Claims 1-9, 12-19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 96/14737 [34] or WO 96/39818 [35] or US 5,691,132 [21] in light of US 5,232,844 [11].

WO 96/14737 or WO 96/39818 or US 5,232,844 disclose in Examples 5, 6, 9-11 and others, a red blood cell suspension in Adsol incubated with quinacrine mustard for various times such as 4 hours. Adsol contains mannitol which is a well known quencher, see US 5,232,844, col. 8, l. 19. With regard to the concentration limitations and ratios of pathogenicidal compound to quencher, in the absence of evidence to the contrary, these are assumed to be the same as disclosed in the reference.

The elected species **together**, aziridinium ion coupled with the nucleic acid binding ligand, acridine and the generic quencher, a thiol, as in claim 11 appear to be free of the art. If these elements are brought into claim 1, it would be directed to matter free of the art.

The examiner selected a next quencher species for examination, mannitol, as is consistent with election of species practice.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted

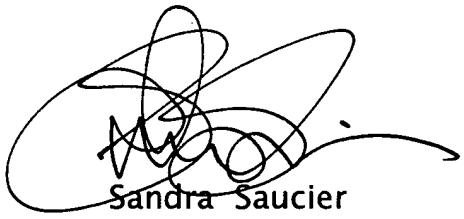
that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to the office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sandra Saucier
Primary Examiner
Art Unit 1651
November 15, 2006